

Food and Drug Administration, HHS

§ 558.35

Drug sponsor	Type A article	Species	Use levels	Indications for use
Do	Zoalene, roxarsone, and penicillin.do	0.0125 percent, 0.0025 to 0.005 percent, and 2.4 to 50 g/ton.	Do.
Do	Zoalene, arsanilic acid, and bacitracin methylene disalicylate or bacitracin zinc.do	0.0125 percent, 0.01 percent, and 4 to 50 g/ton.	Do.
Do	Zoalene, arsanilic acid, and penicillin.do	0.0125 percent, 0.01 percent, and 2.4 to 50 g/ton.	Do.
Do	Zoalene, and bacitracin methylene disalicylate.do	0.004 to 0.0125 percent and 4 to 50 g/ton.	Do.
Do	Zoalene, roxarsone, and bacitracin methylene disalicylate.do	0.004 to 0.0125 percent, 0.0025 to 0.005 percent, and 4 to 50 g/ton.	Do.
Whitmoyer Labs, Inc	Carbarsone and bacitracin.	Turkeys	Sec. 558.120	Sec. 558.120.
Elanco Products Co.	Hygromycin B and tylosin.	Chickens	8 to 12 g/ton and 4 to 50 g/ton.	Sec. 558.274.
Dodo	Swine	12 g/ton and 10 to 100 g/ton.	Do.
A. L. Laboratories, Inc.	Nitarosone and bacitracin zinc.	Turkeys	0.01875 percent, 4 to 50 g/ton.	As an aid in the prevention of blackhead. To increase rate of weight gain and improve feed efficiency.

[51 FR 8811, Mar. 14, 1986; 51 FR 11014, Apr. 1, 1986, as amended at 51 FR 28547, Aug. 8, 1986; 53 FR 20843, June 7, 1988; 54 FR 37098, Sept. 7, 1989; 54 FR 51386, Dec. 15, 1989; 55 FR 8460, 8462, Mar. 8, 1990; 56 FR 41912, Aug. 23, 1991; 56 FR 64702, Dec. 12, 1991; 57 FR 6476, Feb. 25, 1992; 57 FR 8577, Mar. 11, 1992; 57 FR 14639, Apr. 22, 1992; 58 FR 17515, Apr. 5, 1993; 58 FR 30119, May 26, 1993; 61 FR 51589, Oct. 3, 1996; 64 FR 992, Jan. 7, 1999; 64 FR 37673, July 13, 1999]

Subpart B—Specific New Animal Drugs for Use in Animal Feeds

§ 558.35 Aklomide.

(a) *Approvals.* Type A medicated articles: to 053501 in §510.600(c) of this chapter, as follows:

- (1) 50 percent aklomide.
- (2) 20 percent sulfanitran and 25 percent aklomide.
- (3) 25 percent aklomide, 20 percent sulfanitran, and 5 percent roxarsone.
- (4) 50 percent aklomide and 10 percent roxarsone.

(b) *Related tolerances.* See §556.30 of this chapter.

(c) *Conditions of use.* It is used in feed for chickens as follows:

(1) *Amount per ton.* Aklomide, 227 grams (0.025 percent).

(i) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. tenella* and *E. necatrix*.

(ii) *Limitations.* Not to be fed to birds laying eggs for human consumption.

(2) *Amount per ton.* Aklomide, 227 grams (0.025 percent) combined with sulfanitran, 181.6 grams (0.02 percent).

(i) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. tenella*, *E. necatrix*, and *E. acervulina*.

(ii) *Limitations.* Not to be fed to laying chickens; withdraw 5 days before slaughter.

(3) *Amount per ton.* Aklomide, 227 grams (0.025 percent) combined with sulfanitran, 181.6 grams (0.02 percent) + roxarsone, 22.7–45.4 grams (0.0025–0.005 percent).

(i) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. tenella*, *E. necatrix*, and *E. acervulina*; growth promotion and feed efficiency; improving pigmentation.

(ii) *Limitations.* Not to be fed to laying chickens; withdraw 5 days before slaughter; as sole source of organic arsenic; chickens should have access to drinking water at all times.

(4) *Amount per ton.* Aklomide, 227 grams (0.025 percent) combined with

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roxarsone, 22.7–45.4 grams (0.0025–0.005 percent).

(i) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. tenella*, and *E. necatrix*; growth promotion and feed efficiency; improving pigmentation.

(ii) *Limitations.* Not to be fed to birds laying eggs for human consumption; withdraw 5 days before slaughter; as sole source of organic arsenic; chickens should have access to drinking water at all times.

[40 FR 13959, Mar. 27, 1975, as amended at 41 FR 8312, Feb. 25, 1976; 51 FR 7395, Mar. 3, 1986; 55 FR 8460, Mar. 8, 1990]

§ 558.55 Amprolium.

(a) *Approvals.* Type A medicated articles: 25 percent to 050604 in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(b) *Special considerations.* Do not use in Type B or Type C medicated feeds containing bentonite.

(c) *Related tolerances.* See § 556.50 of this chapter.

(d) *Conditions of use—(1) Calves.* It is top-dressed on or thoroughly mixed in the daily feed ration as follows:

(i) *Amount.* 227 milligrams per 100 pounds (5 milligrams per kilogram) body weight per day.

(a) *Indications for use.* As an aid in the prevention of coccidiosis caused by *Eimeria bovis* and *E. zurnii*.

(b) *Limitations.* Administer from a Type B feed containing from 0.05 to 1.25 percent amprolium with the usual amount of feed consumed in 1 day; feed for 21 days during periods of exposure or when experience indicates that coccidiosis is likely to be a hazard; withdraw 24 hours before slaughter; as sole source of amprolium.

(ii) *Amount.* 454 milligrams per 100 pounds (10 milligrams per kilogram) body weight per day.

(a) *Indications for use.* As an aid in the treatment of coccidiosis caused by *Eimeria bovis* and *E. zurnii*.

(b) *Limitations.* Administer from a Type B feed containing from 0.05 to 1.25 percent amprolium with the usual amount of feed consumed in 1 day; feed for 5 days; for a satisfactory diagnosis, a microscopic examination of the feces should be done by a veterinarian or diagnostic laboratory before treatment; when treating outbreaks, the drug should be administered promptly after diagnosis is determined; withdraw 24 hours before slaughter; as sole source of amprolium.

(2) *Chickens and turkeys.* It is used as follows:

Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 36.3 to 113.5 (0.004% to 0.0125%).		Replacement chickens; development of active immunity to coccidiosis.	Feed as follows—	

Growing conditions	Up to 5 weeks of age	From 5 to 8 weeks of age	Over 8 weeks of age
	<i>Amprolium grams per ton</i>	<i>Amprolium grams per ton</i>	<i>Amprolium grams per ton</i>
Severe exposure to coccidiosis.	113.5 (0.0125%)	72.6–113.5 (0.008%–0.0125%)	36.3–113.5 (0.004%–0.0125%)
Moderate exposure to coccidiosis.	72.6–113.5 (0.008%–0.0125%)	54.5–113.5 (0.006%–0.0125%)	36.3–113.5 (0.004%–0.0125%)
Slight exposure to coccidiosis.	36.3–113.5 (0.004%–0.0125%)	36.3–113.5 (0.004%–0.0125%)	36.3–113.5 (0.004%–0.0125%)